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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GAMBEL, PHILLIP

ART UNIT PAPER NUMBER

1644

DATE MAILED: 10/03/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. <u>09/877987</u>	Applicant(s) <u>TO WILSON D</u>	
	Examiner <u>GAMDEL</u>	Art Unit <u>1644</u>	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on \_\_\_\_.

2a) ☐ This action is FINAL.      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_ is/are objected to.

8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner. SEE OFFICE ACTION

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All   b) ☐ Some \*   c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other:
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Serial No. 09/877987  
Art Unit 1644

#### DETAILED ACTION

1. Applicant's amendment, filed 3/4/03 (Paper No. 16), has been entered.  
Claims 6, 23, 31 have been amended.

2. Previously, applicant's election with traverse of Group I and the species of agent one is soluble CTLA4, the species of agent two is anti-CD154 antibody and the species of agent 3 is anti-LFA-1 antibody in Paper No. 11 was acknowledged. The traversal was on the ground(s) that Group I-II are classified in the same classes and separate prosecution of the these claims would be unnecessarily duplicative. This was not found persuasive because of the inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed (see MPEP 806.05-806.05(I)) for the reasons of record set forth in the Restriction Requirement (Paper No. 10). Also, the inventions require non-coextensive searches whether or not the classifications alone are coextensive.

It is noted that claim 36 is in the non-elected Group II.

Therefore, claims 1-9 and 11-18 are under consideration in the instant application rather than applicant's assertions that the elected invention read on claims 1-9, 11-26, 28-34 and 36.

Claims 10, and 19-36 are withdrawn from consideration as being drawn to the nonelected invention and species.

Applicant's amendment, filed 3/4/03 (Paper No. 16) asserts that there was no explanation why claim 10 was withdrawn from the elected invention.

Given the election of anti-LFA-1 antibody as agent 3 in the species election, claim 10 does not recite antibodies that bind LFA-1

3. Upon a review of the instant, the following species election is set forth as it reads on the elected invention and species. The examiner apologizes for any inconvenience to applicant in this matter.

This application contains claims directed to the following patentably distinct species of the claimed Group I wherein the targeted disease or condition is selected from transplant rejection or one of the diseases set forth in claim 13 (as correctly pointed out by applicant and not as claim 30 indicated previously).

Applicant's election of "immune disorders associated with transplant rejection" with traverse in Paper No. 16, filed 3/4/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Serial No. 09/877987  
Art Unit 1644

In determining what was intended by "immune disorders associated with transplant rejection", it is noted that pages 12-13 of the instant specification discloses that this phrase encompasses "chronic rejection, tissue or cell allo- or xenografts including solid organs, skin, islets, muscles, hepatocytes, neurons, etc.).

Therefore, applicant should elect a species "immune disorders associated with transplant rejection"

- (1) between allografts or xenografts AND
- (2) between skin, islets, muscles, hepatocytes or. neurons.

These species are distinct because their etiologies and therapeutic endpoints are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic, for example.

4. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Serial No. 09/877987  
Art Unit 1644

7. Applicant's provision of the citations to the commercial availability of certain hybridomas to the ATCC in Paper No. 16, filed 3/4/03 is acknowledged.

A determination of the public availability and the absence of any restrictions on the public availability of these hybridomas with respect to the enablement requirements under 35 USC 112, first paragraph, for the deposit of the pertinent cell lines / hybridomas which produce the claimed antibodies. (see 37 CFR 1.801-1.809) will be made during examination.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

*Phillip Gambel*

Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
May 19, 2003